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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,108	03/24/2004	Kevin S. Marchitto	D6476CIP	4168

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EXAMINER

WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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03/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/808,108	Applicant(s) MARCHITTO ET AL.	
	Examiner CATHERINE N. WITCZAK	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 and 53-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Priority***

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/670,618 and 60/413,351, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. There is no support in the prior filed application for the limitations of claims 47 and 48 which are drawn to a method of monitoring comprising the use of magnetic fields and eddy currents. As such, these limitations will only be given priority to the filing date of the current application (3/24/2004).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 34-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations of claim 34: 'contacting the tissue at a site of interest with the surface of the applicator of a device comprising an applicator with a surface disposed to contact the tissue' and 'actuating said applicator comprising said device' make the claim indefinite. The first limitation appears to recite a device having an applicator. The second limitation appears to recite an applicator having a

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device. The two limitations contradict each other, making the claim indefinite. Furthermore, the overall language of the claim is redundant (specifically the first limitation), making the claim difficult to comprehend. Appropriate correction is required. For the purpose of the examination and preparation of the current office action, Examiner has interpreted the device used in the method for ablating tissue as claimed in claim 34 to recite a device comprising an applicator; the applicator comprising a tissue contacting surface; and a means to drive the applicator.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 34-46, and 49-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al (US 2003/0208235).

Miller et al disclose a method comprising the steps of contacting a tissue with an applicator actuated by a driving means (paragraph [0087] where Miller et al disclose the use techniques which remove tissue as being a used in conjunction with iontophoresis) which is performed in conjunction with the iontophoresis; dispensing a pharmaceutical while altering the tissue (paragraph [0072-0074]); monitoring electrical current between an active and return electrode; applying electrically conductive fluid interface between the electrode and the tissue (paragraphs [0048-0050]); and controlling the device via a microprocessor in a controller (paragraph [0063]).

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3. Claims 34-42, and 47-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Handy et al (US 2003/0032995).

Handy et al disclose a method comprising the steps of contacting a tissue with an applicator (900a) actuated by a driving means (paragraph [0127] – a solenoid); dispensing a pharmaceutical while altering the tissue (paragraph [0082]); generating and monitoring eddy currents to control the device via a microprocessor in a controller (paragraph [0066]).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 34-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 12/321885 and claims 1 and 34-37 of copending Application No. 10/670618. Although the conflicting claims are not identical, they are not patentably distinct from each other because the each disclose methods of treating tissue comprising the steps of contacting the tissue with an actuated applicator and monitoring an electrical property of the tissue during treatment.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 11/16/09 have been fully considered but they are not persuasive.

In response to Applicant's arguments regarding priority, the disclosure that electromagnetic energy may induce alteration of the stratum corneum and the use of multiple electrodes to measure the electrical properties of the treatment site and provide feedback to the device found in the prior filed applications does not provide adequate support for the limitations drawn to generating and monitoring eddy currents, and correlating the eddy currents with electrical conductivity of the tissue.

As to Applicant's arguments regarding the Miller et al reference, Examiner points out that while Miller et al disclose an iontophoretic device, the reference also discloses the use of a tissue ablating means to aid in the effectiveness of the iontophoretic treatment. Thus, Miller et al disclose a method of ablating tissue. As for Applicant's arguments that Miller et al only disclose monitoring and controlling electrical resistance to control the electrical parameters at the iontophoretic electrodes, Examiner points out that the limitation reads "wherein the electrical property of tissues are monitored in order to monitor the tissue alteration process." The method of Miller et al comprises two tissue alteration steps: one being tissue alteration resulting from iontophoresis, the other resulting from tissue ablation. As Applicant has not claimed a specific alteration process which is monitored, the Miller et al reference is considered to teach the claimed limitations.

Applicant further argues that Handy et al do not teach of method of ablating tissue in order to increase the permeability of skin. Examiner disagrees. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a method of increasing the permeability of skin) are not recited in the rejected

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claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As to Applicant's arguments that Handy et al do not teach a method of ablating tissue, Examiner points out that the device and method of Handy et al is drawn to a method of using magnetically induced thermotherapy (thermo-ablation, see paragraph [0012] to destroy diseased cells.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witzak/
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767